Actilyse®

alteplase

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Actilyse.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with Actilyse against the benefits they expect it will have for you.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

If you have any concerns about being treated with this medicine, ask your doctor or pharmacist.

Keep this information with the medicine.
You may need to read it again.

What Actilyse is used for

Actilyse is used to treat a number of conditions caused by blood clots forming within blood vessels, including:

- heart attacks caused by blood clots in the arteries of the heart (myocardial infarction)
- blood clots in the arteries of the lungs (pulmonary embolism)
- stroke caused by a blood clot in an artery of the brain (acute ischaemic stroke).

Actilyse contains the active ingredient alteplase. It belongs to a group of medicines called thrombolytic agents.

Actilyse works by dissolving clots in the blood vessels. These clots cause disease by interfering with normal blood flow.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

Before you are given Actilyse

When you must not be given it

You should not be given Actilyse if you have an allergy to:

- any medicine containing alteplase (the active ingredient in Actilyse)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Because of the risk of bleeding, Actilyse should not be given to you if you have, or have had:

- current bleeding or severe bleeding in the past 6 months
- a family history of bleeding disorders or a tendency to bleed
- a previous condition resulting in bleeding or suspected bleeding in the brain
- heart and lung resuscitation, childbirth, organ biopsy or an invasive medical procedure in the past 10 days
- major surgery, including heart, head or spinal surgery, or significant trauma (including trauma to the head) in the past 3 months
- severe and uncontrolled high blood pressure
- tumours in which the risk of bleeding is increased
- any blood clotting defect
- current treatment with other thrombolytic agents (medicines used for dissolving blood clots) or an anti-clotting agent (anticoagulant), such as warfarin
- certain diseases of the blood vessels, heart, brain, oesophagus, stomach/intestine, liver, kidney or pancreas in which the risk of bleeding is increased
- serious liver problems.

In addition to the above medical conditions, Actilyse should not be used for the treatment of heart attack or pulmonary embolism if you have, or have had:

- a stroke caused by bleeding in the brain (condition known as haemorrhagic stroke) or a stroke of unknown origin at any time
- a stroke caused by a blood clot in the artery of the brain (condition known as ischaemic

stroke) or a transient ischaemic attack (TIA) in the past 6 months, unless the symptoms of your stroke occurred within the past 4.5 hours and you are about to be treated for it.

Actilyse should not be used for the treatment of acute ischaemic stroke if you have, or have had:

- experienced the symptoms of your stroke for more than 4.5 hours or if you do not know when they began
- mild neurological symptoms or when the symptoms are rapidly improving before receiving Actilyse
- a very severe stroke
- any signs of bleeding in the brain or any condition that increases the risk of bleeding in the brain
- fits or seizures at the onset of stroke
- treatment with heparin in the past 48 hours (and your bleeding time is abnormal)
- previous stroke or serious head injury/trauma within the last 3 months
- previous stroke and you are diabetic
- a low platelet count (platelets are blood cells involved in blood clotting)
- severe high blood pressure (over 185/110 mmHg)
- very low sugar (glucose) level in your blood (under 50 mg/dL or under 2.8 mmol/L) or very high sugar level in your blood (over 400 mg/dL or over 22.2 mmol/L).

This medicine must not be given to a child or adolescent under the age of 18 years.
Safety and effectiveness in children and adolescents younger than 18 years have not been established.

Actilyse should not be used after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

It is important that your doctor knows your medical history before administering Actilyse.

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following conditions:

- a previous heart attack or any other heart condition
- a previous stroke caused by a blood clot in the brain or a transient ischaemic attack (TIA) more than 6 months previously (this only applies if you are being treated for heart attack or pulmonary embolism)
- diabetes mellitus
- bleeding from inside or around your eyes or visual disturbances
- high blood pressure
- severe liver disease
- any recent medical procedure such as a biopsy or injection.

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.
Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are over the age of 70 years.

The risks of treatment with Actilyse may be increased in patients over 70 years if they have, or have had, high blood pressure, or in any patient over 80 years of age.

Before starting treatment with Actilyse your doctor will assess other factors which may increase the risks of using Actilyse. Your doctor will take special care with Actilyse if you have or have had:

- any infected veins and cannula sites
- any condition in which bleeding is a significant risk or would be particularly difficult to manage because of its location
- ever received Actilyse before.

If you have not told your doctor about any of the above, tell him/her before you are given Actilyse.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Actilyse may interfere with each other. These include:

- aspirin, heparin, warfarin or any other medicines used to "thin" the blood and prevent blood clots
- ACE inhibitors, a group of medicines used to treat high blood pressure.

These medicines may be affected by Actilyse or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How Actilyse is given

Actilyse will be prepared and administered to you by your doctor or by a healthcare professional. It is not for self-administration.

Treatment with Actilyse should be initiated as soon as possible after the start of your symptoms.

Actilyse is supplied as a powder and sterilised water for injections. Before use, the water for injections

is added to the powder to form a solution ready for administration. This solution is given into a vein through a drip line.

How much is given

The recommended dose is 100 mg given over 90 or 180 minutes for a heart attack, or over 120 minutes for pulmonary embolism. A lower dose (1.5 mg/kg) is recommended for patients weighing less than 65 kg. No more than 100 mg should be given because it is associated with a higher risk of bleeding (especially in the brain).

For treatment of acute ischaemic stroke a dose equivalent to 0.9 mg/kg body weight is given over 60 minutes. The maximum dosage should not exceed 90 mg.

Your doctor might prescribe a different dose or duration of treatment to that described here. If you want more information, ask your doctor.

If you are given too much (overdose)

Overdose is unlikely because Actilyse is administered under medical supervision.

Symptoms of an overdose may include bleeding.

In the case of serious bleeding, your doctor will immediately stop treatment with Actilyse and heparin. Your doctor will start appropriate treatment to control the bleeding and, if necessary, replace the lost blood.

While you are being given Actilyse

Things you must not do

You should not take aspirin for the first 24 hours after treatment with Actilyse. Your doctor may give you an injection with heparin if this is necessary.

Things to be careful of

Actilyse increases the risk of bleeding and bruising. After treatment with Actilyse medical staff will avoid giving you injections or moving you unless absolutely necessary.

Your doctor will probably continue to treat you with heparin and aspirin after treatment with Actilyse. This is to reduce the risk of more blood clots forming.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given Actilyse.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 80 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

If any of the following happen, tell your doctor immediately:

- bleeding or blood clot within the head or brain. Symptoms may include collapse, sleepiness, difficulty in speaking or slurred speech, numbness or weakness of the arms or legs, headache, dizziness, visual disturbance, confusion, loss of memory, agitation, depression, weakness on one side of the body, convulsions, fits or seizures, psychosis, a severe mental condition in which the person loses contact with reality and is unable to think and judge clearly, difficulty swallowing
- bleeding from the skin, mouth, gums, nose, or eyes
- bruising
- bleeding or bruising where the injection is given
- nausea, vomiting or vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- blood in the urine
- coughing up blood
- changes in heart rate (fast, slow or irregular), extra heart beats, weak pulse
- chest pain, pain behind the breast bone, sometimes spreading to the neck and shoulders
- shortness of breath, tiring easily after light physical activity such as walking, waking up short of breath at night
- rapid, shallow breathing
- cold, clammy or white skin
- light-headedness
- weakness
- fluid retention in different parts of the body, often first noticed as swollen ankles and feet
- restlessness
- any symptoms of an allergic reaction (e.g. rash, itching, hives on the skin, swelling of the face, lips, mouth, tongue, throat or other parts of the body, shortness of breath, wheezing or difficulty swallowing or breathing)
- high body temperature.

Due to the life-threatening nature of the diseases for which Actilyse is used, some deaths have occurred

after treatment. However, use of Actilyse in large numbers of patients has shown that when used as recommended, the benefits outweigh the risks.

There have also been reports of blockages of blood vessels following treatment with Actilyse. This can lead to organ failure (e.g. kidney failure).

Nausea and vomiting can occur after a heart attack and may or may not be increased by Actilyse.

The above list includes very serious side effects. You may need urgent medical attention.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given Actilyse

Storage

Actilyse will be stored in the pharmacy or on the ward below 30°C and protected from light.

After mixing with sterilised water for injections, Actilyse should be used immediately. If not used immediately, the product may be stored in a refrigerator (2-8°C) and used within 24 hours.

Disposal

Actilyse is for single use only and any unused solution must be discarded.

Product Description

What it looks like

Actilyse is the brand name of your medicine. It comes as a sterile white to off-white powder in clear glass vials containing 10 mg (corresponding to 5,800,000 IU), 20 mg (corresponding to 11,600,000 IU) or 50 mg (corresponding to 29,000,000 IU) alteplase.

Actilyse powder must be mixed with sterilised water for injections before use. When mixed, the resulting solution is colourless to pale yellow.

Actilyse is available as a pack containing one vial of powder and one vial of sterilised water for injections.

Actilyse is available in the following pack sizes:

- One vial of powder with 10 mg alteplase and one vial with 10 mL of sterilised Water for Injections
- One vial of powder with *20 mg alteplase and one vial with 20 mL of sterilised Water for Injections
- One vial of powder with 50 mg alteplase and one vial with 50 mL of sterilised Water for Injections.

* Not distributed in Australia.

Ingredients

Actilyse powder contains 10 mg, 20 mg or 50 mg of alteplase as the active ingredient.

It also contains:

- arginine
- phosphoric acid
- polysorbate 80
- nitrogen.

Sodium hydroxide or phosphoric acid may be added to adjust the acidity of Actilyse.

Supplier

Actilyse is supplied in Australia by:

Boehringer Ingelheim Pty Limited
ABN 52 000 452 308
Sydney, Australia
www.boehringer-ingelheim.com.au

This Consumer Medicine Information was updated in October 2023.

Australian Registration Numbers

10 mg vial - AUST R 64240

20 mg vial - AUST R 43375

50 mg vial - AUST R 17905